MEDICAL AI AT RISK: DIGITAL OMNIBUS AMENDMENTS UNDERMINE SAFEGUARDS IN HEALTHCARE

Members of the European Parliament are about to take a decision that will fundamentally shape how artificial intelligence (AI) is governed in European healthcare. The Internal Market and Consumer Protection (IMCO) and Civil Liberties, Justice and Home Affairs (LIBE) compromise amendments propose deleting Annex I, Section A of the AI Act and shift medical devices into Annex I, Section B. If adopted, AI medical devices would remain labelled as "high-risk", but would no longer be subject to meaningful high-risk obligations.

In a domain where AI directly affects diagnosis, treatment, and patient health, this creates a serious regulatory gap with real risks for patients. The proposed solution – "mirroring" AI Act requirements into the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) – does not address this gap, as it makes safeguards dependent on future delegated acts and standards, with no guarantee as to their timing or scope. This risks delaying and weakening protections while medical AI systems are already in use.

This is not "simplification", but a structural weakening of safeguards for medical AI.

Members of the European Parliament should reject Amendments 31(a) and 31(b) to preserve effective and timely protection of patient safety and fundamental rights.

It is essential to keep AI medical devices within the core high-risk regime of the Artificial Intelligence Act for four key reasons:

1. AI safeguards are needed now – not at an uncertain point in the future

AI systems are already being used in clinical practice, where they influence diagnosis, treatment, and access to care. Safeguards must therefore apply immediately and in a clear, enforceable way. Keeping medical AI within the AI Act ensures that requirements on data governance, risk management, human oversight, and monitoring apply from the outset. By contrast, "mirroring" these safeguards into the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) makes them dependent on future delegated acts and standards, with no guarantee as to their timing or scope. **This risks delaying protection while AI systems are already shaping patient care in practice**.[1]

2. AI introduces risks that traditional product safety law does not capture

Medical device legislation is designed to assess safety and performance of products, but it does not fully address the specific risks associated with AI systems. These include issues including biased training data, lack of transparency, and unequal outcomes across patient groups. The AI Act complements product safety law by

introducing safeguards tailored to these risks and by incorporating a broader fundamental rights perspective. **Removing these safeguards narrows the regulatory framework to a traditional safety-performance model that is not equipped to govern the real-world impact of AI in healthcare**.[2]

3. Health professionals need clear obligations about AI use

Many risks associated with AI do not arise at the moment a device is placed on the market, but when it is used in clinical practice by health professionals. The current AI Act recognises this by regulating both providers and deployers, including healthcare institutions that integrate AI into clinical workflows, and by requiring monitoring, training, and appropriate use. The MDR/IVDR, by contrast, focus primarily on manufacturers and do not impose comparable obligations on those deploying AI in healthcare settings. This creates a regulatory gap at the point where decisions are made and patients are affected.

Without clear obligations on deployers, hospitals lack requirements to ensure proper integration, monitoring, and staff training, while clinicians are left without clear guidance on when to rely on AI and when to question it. As emphasised by the Standing Committee of European Doctors, removing obligations on deployers and AI literacy risks leaving healthcare professionals without the necessary support to use AI systems safely and responsibly in practice.[3] **In healthcare, safety does not depend only on how an AI system is designed, but on how it is used by health professionals.**

4. This will not simplify the law – it will create fragmentation and delay innovation

These amendments do not simplify the law, but shift complexity elsewhere. The AI Act was specifically designed to work alongside sectoral legislation such as the MDR/IVDR, allowing compliance to be integrated into existing conformity assessment procedures rather than creating a parallel system.[4]

Removing medical AI from the core high-risk regime does not eliminate duplication. It shifts AI governance into multiple sectoral frameworks, where safeguards would need to be reintroduced over time through delegated acts and guidance. This risks creating fragmentation, legal uncertainty, and inconsistent standards across sectors. In a field as sensitive as healthcare, such uncertainty can also delay the adoption of AI, as trust in the safety and reliability of these systems is a precondition for their uptake.

References

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